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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,199	04/15/2004	Itzhak Kronzon	50129/00202	9818
30636 7590 05/03/2007 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038			EXAMINER FLORY, CHRISTOPHER A	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,199	KRONZON, ITZHAK	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-15 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-15 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 29 December 2006. These drawings are acceptable.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1-5, 7, 8, 10, 12-15 and 17-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Friedman (US Patent Publication 2003/0097167, hereinafter referred to as Friedman'167).**

Regarding claims 1-5, 10, 14 and 19, Friedman'167 discloses a medical apparatus used to treat cardiac arrhythmia comprising a flexible probe for accessing a patient's esophagus via the mouth with a proximal end which remains outside the patient and a distal end within the esophagus (TITLE; ABSTRACT; paragraphs [7], [10] and [32]); an echocardiography transducer coupled to the distal end at a predetermined location within the esophagus relative to the heart to perform transesophageal echocardiography (Fig. 1 TEE probe 3; paragraphs [6], [10] and [32]); and a plurality of

electrodes spaced along a longitudinal axis of the probe included in the sheath (Fig. 2, electrodes 26; Fig. 3, leads 1-8) each coupled to a wire lead extending along the probe to a power source (paragraphs [9], [28] and [29]) for delivering a cardioversion or defibrillation current via the esophagus (paragraphs [15]-[17] and [36]-[38]).

Regarding claims 7, 17 and 18, and further regarding claims 1 and 14, Friedman'167 discloses the electrodes mounted on or within a flexible sheath which is sized to be received over a distal portion of the probe and fixed thereon at a predetermined location relative to the echocardiography transducer (paragraphs [6], [7], [10]-[12] and [32]), the sheath being made of a biocompatible material (paragraph [32] discloses a sheath made of silicone) wherein the sheath/electrode is selectively mountable on and removable from the scope portion (paragraphs [11], [12] and [32]). It is noted that the electrical contacts within the sheath are functional as electrodes in an operative position themselves, and also that the act of clamping the electrode rings to the sheath can be reasonably interpreted to mean a sheath including an electrode.

Regarding claim 8, Friedman'167 discloses that the sheath can also be permanently bonded to the probe (paragraphs [34] and [35]).

Regarding claims 12 and 13, Friedman'167 discloses the electrode having a length of 7-10mm along an axial direction of the probe and being separated from a second electrode by a distance of 5-8mm (Fig. 3).

Regarding claim 15, Friedman'167 discloses an electrode assembly that is one of a single use assembly and a multiple use assembly, in that a single use assembly is defined identically to a removable and selectively mountable assembly, and a multiple

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use assembly is synonymous with a permanently bonded assembly as discussed with regards to claim 6, 8 and 9.

Regarding claim 20, Friedman'167 discloses a method of treating a heart of a patient comprising the steps of inserting a flexible echocardiography probe into the patient's esophagus, performing an echocardiography to analyze the condition of the heart, and applying electric current to the at least one cardioversion electrode to supply a current to the heart (paragraphs [13]-[17]).

Regarding claim 21, Friedman'167 discloses performing an additional echocardiography immediately after the cardioversion using the echocardiography transducer (paragraph [18]).

Regarding claims 22 and 23, Friedman'167 discloses coupling the electrode sheath to the probe prior to inserting the device into the esophagus and disposing of the sheath after completing the procedure (paragraphs [6], [7], [10], [11], [12], [32] and [33]).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167.**

Regarding claim 11, Friedman'167 discloses the invention substantially as claimed but does not expressly disclose that the electrode is formed of a titanium foil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method as taught by Friedman'167 with a titanium foil electrode, since it is well known in the art that titanium is a good material for electrode construction due to its relatively low cost, durability, biocompatibility, and good electrical conduction properties.

Response to Arguments

6. Applicant's arguments, see paragraph 2 of page 7, filed 29 December 2006, with respect to the objection to the drawings have been fully considered and are persuasive. The objection to the drawings has been withdrawn.

7. Applicant's arguments, see paragraph 3 on page 7, filed 29 December 2006, with respect to the rejection of claims 5 and 18 under 35 U.S.C. §112, second paragraph have been fully considered and are persuasive. The §112 rejection of claims 5 and 18 has been withdrawn.

8. Applicant's arguments filed 29 December 2006 have been fully considered but they are not persuasive. Claims 1-5, 7, 8, 10, 12-15 and 17-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Friedman'167.

In response to Applicant's argument that Friedman'167 fails to disclose a sheath and electrodes as a single unit, it is noted that the electrical contacts within the sheath are capable of function as electrodes. It is further noted that, as written, the claims are

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anticipated by Friedman'167 since the act of clamping the electrode rings to the silicone sheath as disclosed in Friedman'167 can also be reasonably interpreted to mean "a sheath including an electrode" as is written in the instant claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., strategic placement of the electrodes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the recitation of "an operative position" merely limits the electrodes to being placed in a position in which they are functional to stimulate the esophagus. The electrodes as disclosed in Friedman'167 are therefore reasonably considered to be operative. Alternatively, the same electrodes can be seen as strategically located, in that they successfully stimulate the esophageal tissue, which is their disclosed use.

While the rejection of claims 14 and 20 has also been specifically traversed, no arguments on the merits of said claims have been set forth. Examiner therefore assumes that the arguments posed on the similar rejection of claim 1 are intended to be directed to claims 14 and 20 as well. Therefore, the Examiner takes the position that claims 14 and 20 stand properly rejected under 35 U.S.C. §102(e) for reasons similar to those stated with regard to claim 1 above.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

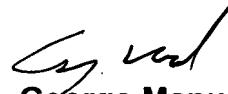
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

17 April 2007


George Manuel
Primary Examiner